Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	[redacted]
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	280502
PERSON INTERVIEWED:	JoEllen Embry and Raymond Embry
PLACE OF INTERVIEW:	[redacted]
DATE OF INTERVIEW:	03/03/2020
TIME OF INTERVIEW:	4:45 PM
INTERVIEWED BY:	ASAIC George Scavdis
OTHER PERSONS PRESENT:	See below.

On March 3, 2020, the case agent interviewed JoEllen Embry and Raymond Embry regarding Theranos, Inc. Also present during the interview was AUSA John Bostic, United States Attorney's Office for the Northern District of California, San Jose, California.

JoEllen Embry is a women's health nurse practitioner and is the owner of Embry Women's Health located [redacted] Ms. Embry has been working in women's health since 1983. Since 1996, she has been a nurse practitioner. In February 2014, she opened her own practice. She does everything pertaining to women's health, with an emphasis on endocrine problems.

At one point in time, Ms. Embry was ordering the most Theranos blood tests in the Phoenix, Arizona, area. Ms. Embry said she almost wrote a letter to the Wall Street Journal because she knew something was wrong with Theranos from the first few months that she started using them.

When a patient first comes to Ms. Embry, she orders a large panel of blood tests. Many times, her patients suffer from irregular or no periods, really high testosterone, bald spots, acne, and facial hair. These are all symptoms of polycystic ovarian syndrome (PCOS). Within three or four months of using Theranos, Ms. Embry discovered a problem. Some of her patients have "man levels" of testosterone. A testosterone level of 30 to 40 is normal, and some of the women she saw had a value of 120. She would place them on medication to lower their levels of testosterone. These patients were getting blood tests at Theranos and their testosterone levels were showing a value of less than one.

Ms. Embry used both Sonora Quest and LabCorp. before she used Theranos, and she did so for approximately twenty years. Any errors in lab results with those laboratories were administrative errors, not clinical ones. She had no problems with the results. She said with Sonora Quest, there was a period when parathyroid or prolactin values were coming back for her patients as being slightly elevated. Sonora Quest corrected the problem. Ms. Embry said there could have been a clinical explanation for the elevated values, because often it is correlated to Vitamin D levels in a patient. Once she gets the Vitamin D levels up, the level of prolactin or parathyroid comes back down; that could be an explanation for the Sonra Quest results. This is the only "issue" that she can think of with Sonra Quest lab results, and it only lasted for a short period of time.

Also, it's the only issue she's ever had with any other laboratory, aside from Theranos. She did not lose confidence in Sonora Quest after this.

Mr. Embry said that the practice reported a patient safety issue on March 11, 2015, to Theranos. In response, Theranos initiated a conference call that included Elizabeth Holmes's brother (later identified as Christian Holmes, and hereinafter referred to as Mr. Holmes). The result of that conference call was that it gave the practice enough confidence to continue to use Theranos until the Fall of 2015. Once Ms. Embry sees a pattern of errors with someone, she calls them on it and gives them a chance to correct the problem.

Ms. Embry said that she was screaming at Mr. Holmes during the conference call. His response was to say that Theranos had protocols in place. She asked him, "How can you explain that?" He responded, "Well, you fixed them." Mr. Holmes explained the low testosterone values saying, "We found out our machines were not calibrated for venous draws, they were calibrated for finger stick." Ms. Embry responded, "My patients never had finger stick draws." Mr. Holmes responded, "We'll figure this out." Mr. Holmes eventually got back to Ms. Embry and said that it was a calibration issue. After that, the laboratory results started coming back more in line with what Ms. Embry expected.

Ms. Embry recounted how she first learned of Theranos. She said that a Theranos sales representative came into the office. Mr. Embry said the representative was Kyle Johnson and he was a senior account executive. He said Mr. Johnson's first contact with the office was on June 18, 2014. Ms. Embry said that the finger stick was never a draw for her because she didn't believe Theranos could do it accurately. She was attracted to the convenience and the affordability of their tests. Ms. Embry doesn't recall if Mr. Johnson made representations about the accuracy or reliability of Theranos's tests. She thinks it's implied that if a laboratory is offering lab tests that the results will be accurate.

Mr. Embry said he recalled when officials from the State of Arizona were taking pictures with people from Theranos and he remembers when the partnership with Walgreens went into effect. Theranos representatives continued to talk about partnerships it had, including a partnership with the Mayo Clinic. They said they were working together with the Mayo Clinic on certain test expansion. Theranos talked about the background of their scientists that worked on their machines, and how these were top people in their fields. They talked about their investors and how they were putting money behind Theranos. Ms. Embry doesn't recall any Theranos representatives ever talking about a partnership with the United States Department of Defense.

Mr. Embry said Theranos talked about validation of their finger stick technology. In 2014, all the Theranos marketing was about finger stick. It took him several months to realize that none of their test were being performed via finger stick blood draw. They gave some indication that their technology was approved by the Government, either through CLIA or the FDA.

Ms. Embry explained that Theranos would interface with her practice, and the practice would get results loaded directly into their system. At one point, she was sending patients exclusively to Theranos. The number of tests she ordered per patient was high, and she sent at least 30 separate blood draws to Theranos per week. None of her patients ever had a finger stick blood draw from Theranos. Theranos was saying the blood draw would be via finger stick, but when her patients came back, they told Ms. Embry that they had venous blood draws. Ms. Embry didn't see the finger stick as a big draw. Theranos told her that testing would be conducted via finger stick blood draw, but she knew with the broad range of tests they were offering that it couldn't be done on finger stick. However, it was new information to her when her patients came back to her to tell her that they had venous blood draws as opposed to finger sticks.

In the Fall of 2014, everything was "up and running" between her practice and Theranos and that's when she started to notice the issues with the testosterone tests. She asked her Theranos sales representative about it, and that is when they had the conference call with Mr. Holmes. The call was initiated by Mr. Holmes calling Ms. Embry on her cell phone. Ms. Embry explained that testosterone is a key assay for her practice. The error in the Theranos testosterone results was blatantly obvious. Her patients were coming back with testosterone values less than one and they were growing a beard at the time. It was literally every patient that

was being tested during this time period. This issue surfaced in September 2014.

Ms. Embry also had issues with patients she was sending to Theranos who were testing high for calcium. High calcium has to do with the parathyroid gland and is unrelated to PCOS. Ms. Embry explained that high calcium is unusual and that there was nothing else with her patients that would explain why they would randomly test high for calcium.

When Ms. Embry was talking to Theranos about the testosterone results, she told them that if they didn't fix the issue, that she would stop sending patients to Theranos. She explained to the case agent that she is adjusting patients' medications based on their lab results, and that could have led to a patient being harmed. The problems with the Theranos testosterone assay caused her to doubt their other assays.

There was a third and final issue with Theranos that ultimately led to Ms. Embry terminating the relationship with Theranos. She told them that she thought Theranos was dangerous and that her patients could not use their services anymore. The Theranos sales representative brought her lunch after that and asked her if she saw an e-mail from Theranos that said that some of the lab results weren't accurate. Ms. Embry asked the representative if he was going to call her patients and tell them that, and he responded that it was her responsibility.

Ms. Embry remembers waking up early on a Friday morning to sign off on lab results and she had 1,500 Theranos labs in her inbox. Theranos sent her every lab she ever ordered, saying her results were voided. She was already "done" with Theranos at that point. She never experienced problems like this with previous laboratories.

Ms. Embry talked to the case agent about an experience she had with a testing company called GenPath. She said that all the cervix biopsy results she received back from GenPath were coming back as having chronic cervicitis, or inflammation of the cervix. Also, all her endometrial biopsies were coming back as having endometritis. No abnormal cells were showing up on her tests, yet inflammation was showing up. The head of GenPath called her and said they have processes in place. She called Women's Health Services and they explained that they thought GenPath was only looking at the top two layers of specimen, so of course they're going to see inflammation. They said GenPath was being lazy. Ms. Embry clarified that this is a visual test she is talking about, not a blood test. Ms. Embry never had any issues with blood testing with any other laboratories like she had with Theranos in all her years of practice.

Ms. Embry said that with the erroneous testosterone results, Theranos was marking on its paperwork that the patients weren't fasting, even in instances where they were in fact fasting.

Mr. Embry said that he sent an e-mail to Theranos warning them that they were sending out inaccurate patient results, and he sent that e-mail on March 11, 2015. Erin Porter was the name of the Theranos representative that he sent it to. Overall, there were five different Theranos representatives that interacted with the practice at one point or another. Her patients continued to use Theranos for STD testing through March 2016. Ms. Embry probably stopped sending patients to get panels and testosterone tests in March 2015. Some of her patients went to the Theranos lab draw station located in the Generations Medical Building. Theranos also did mobile lab draws and went directly to the patients.

Ms. Embry explained that they had an EMR system at the practice, which allowed the provider to fill out the lab test order and then synch that up with Theranos's system. Through the EMR system, Theranos test results came back to the practice through the portal. Ms. Embry's practice had nothing to do with the billing of the Theranos blood test.

Ms. Embry said, to this day, she doesn't have any patients that had testosterone as low as Theranos was reporting.

Mr. Embry said that on March 11, 2015, at 1:15 he called and left Theranos a message. He said the practice can export patient testing data and provide that to the Government.

SUBMITTED: Electronically submitted by GEORGESCAVDIS

GEORGE SCAVDIS, ASSISTANT SPECIAL AGENT IN CHARGE DATE: 03/16/2020

APPROVED: Electronically approved by MARKMCCORMACK

MARK MCCORMACK, SPECIAL AGENT IN CHARGE DATE: 03/17/2020

DISTRIBUTION: Orig: MWFO
cc: Prosecution

ATTACHMENTS: None.